Remarks

Applicants would like to thank Examiner Spiegler for the interview of June 26, 2002. In accordance with the outstanding office action and the aforementioned interview, Applicants have herein canceled claims 11, 12, and 14 without prejudice or disclaimer and amended claims 36, 38-56, 61, 66, and 71. The claims have been amended to include antecedent basis corrections and/or to specify that the claimed polypeptides are capable of being used to generate or select an antibody. Support for the claim amendments can be found in the original specification as filed. For example, support for the claim amendments can be found at: page 104, first full paragraph; at page 109, first paragraph; and at page 110, third paragraph to page 113, first paragraph. Thus, no new matter has been introduced.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 11, 12, and 14 were rejected in the currently outstanding Office Action under 35 U.S.C. § 112, second paragraph. *See*, Paper No. 9, page 3. Applicants have herein canceled claims 11, 12, and 14 without prejudice or disclaimer and, therefore, submit that the rejection of these claims has been rendered moot. Applicants reserve the right to pursue the subject matter of claims 11, 12, and 14 in one or more divisional applications.

Claims 30-35, 41-45, 51-55, 61-65 and 71-75 were also rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because the phrases "the secreted portion," "the complete polypeptide," and "the HYACJ27 cDNA" lack antecedent basis. *See*, Paper No. 9, page 3, part 4. Applicants respectfully demur and submit that the claims might actually become indefinite if rigid technical compliance with the M.P.E.P. guidelines was attempted. For example, consider that pending claim 30 currently recites:

> 30. An isolated protein comprising the amino acid sequence of the secreted portion of the polypeptide encoded by the HYACJ27 cDNA contained in ATCC Deposit No. PTA-163.

However, if the phrases "the secreted portion," "the complete polypeptide," and "the HYACJ27 cDNA" were amended in the claims (as requested in the Office Action) to stringently comply with antecedent basis guidelines, then claim 30 would recite:

> 30. An isolated protein comprising the amino acid sequence of a secreted portion of the polypeptide encoded by a HYACJ27 cDNA contained in ATCC Deposit No. PTA-163.

Applicants respectfully submit that such amendments would not only introduce ambiguity, but are also not required by the M.P.E.P. guidelines.

The M.P.E.P. guidelines for proper antecedent basis are primarily concerned with claims containing two or more identically named elements wherein a limitation is applied to *one element* without specific clarification *as to which element* the limitation applies. On the other hand, the guidelines only require explicit antecedent basis if the scope of the claim would not be reasonably ascertainable by those skilled in the art. *See*, M.P.E.P., 8th Ed., § 2173.05(e) ("failure to provide explicit antecedent basis for terms does not always render a claim indefinite.")

Additionally, the guidelines explain that:

> Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation "the outer surface of said sphere" would not require an antecedent recitation that the sphere has an outer surface.

Id at § 2173.05(e).

In this regard, Applicants submit that the phrases "the secreted portion," "the complete polypeptide," and "the HYACI27 cDNA" comprise inherent components of the recited elements. Additionally, because the scope of the claims would be reasonably ascertainable by those skilled in the art, Applicants respectfully submit that the claims, as currently worded, are not indefinite. Accordingly, it is respectfully requested that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn. If the Examiner disagrees with the above explanation, Applicants urge that a telephone conference may be helpful in expeditiously reaching an agreeable solution.

[Applicants note, however, that the claims have been herein amended to include antecedent basis corrections with respect to recitation of the words "protein" and "polypeptide." *See*, Version With Markings To Show Changes Made (submitted herewith).]

Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 11, 12, 14, and 36-75 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *See*, Paper No. 9, page 3, part 6. In particular, it has been alleged that "Claims reciting 90% sequence identity are inclusive of sequences from other species, mutated sequences, and allelic variants having different functional activities than that of the protein in SEQ ID NO:56." *See*, Paper No. 9, page 3, last paragraph to page 4, first paragraph. Additionally,

claims drawn to proteins comprising 30 or 50 contiguous amino acids of SEQ ID NO:56 were rejected because these would allegedly "be expected to have unique functional activities, wherein the specification has not disclosed any proteins having functional activities different from those of SEQ ID NO:56." *See*, Paper No. 9, page 4, first paragraph.

In order to expedite prosecution of the present application, Applicants have herein amended claims 36, 41, 46, 51, 56, 61, 66, and 71 (encompassing polypeptides of at least 90% identity and comprised of 30 or 50 contiguous amino acids) to specify that the claimed polypeptides are capable of being used to generate or select an antibody.

Applicants respectfully disagree, however, that the specification lacks adequate written description for claims drawn to 90% identical polypeptides and polypeptides comprised of 30 or 50 contiguous amino acids. The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. The Federal Circuit has also reaffirmed that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000). *See also* M.P.E.P. § 2163.02 ("The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement."). The Court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. Indeed, as the court noted, "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Unocal*, 208 F.3d at 1001 (emphasis added).

The present case is also quite distinct from the situations considered in *Fiers v. Revel*, *Amgen v. Chugai*, *Fiddes v. Baird*, and *University of California v. Eli Lilly* (cited in Paper No. 9, page 4, last paragraph to page 5, first paragraph). Hence, in the present case applicants have provided polynucleotide and polypeptide sequences (not just a mere statement that these are part of the invention). And, unlike *Fiddes v. Baird*, Applicants have described polynucleotide and polypeptide sequences based on *structural characteristics* readily recognized by those of ordinary skill in the art (*e.g.*, 90% identity, 30 and 50 contiguous amino acids). Moreover, the central issue in *Eli Lilly* involved claims to mammalian cDNAs encoding insulin, which were supported in the specification only by the nucleotide sequence

for the rat insulin gene. The Federal Circuit found the claims lacking in written description because the claims defined only a result or function. The court held that a result or function will satisfy the written description requirement *only if* correlated to a description of structural features of the claimed invention. According to the court, a sufficient written description must allow the skilled artisan to "visualize or recognize the identity of the members of the genus." *Id.* Thus, unlike the situation in *Eli Lilly*, the written description of the present invention does allow the skilled artisan to "visualize or recognize the identity of the members of the genus." As such, the specification does provide adequate written description to enable one of skill in the art to visualize or recognize the identity of the members of the genus because the actual structure (e.g. the polypeptide sequence) of the claimed invention is disclosed. For example, at page 101, line 7, through page 110, line 10, the specification provides substantial written description regarding polypeptide variants, homologues, amino acid deletions, and determination of percent identity. Accordingly, one skilled in the art, when provided teachings of the present application, could readily envision the polypeptide sequences encompassed by the present claims. Indeed, nothing more than a basic knowledge of the genetic code and what is described in the specification would be required for the skilled artisan to readily envision every single one of the polypeptides that are at least 90% identical to the amino acid sequence of SEQ ID NO:56.

Accordingly, from reading the specification, the skilled person would immediately recognize that, at the time the specification was filed, the Applicants had "invented what is claimed" (*Vas-Cath*, 935 F.2d at 1563); namely, a genus of proteins comprising polypeptides with at least 90% identity to the polypeptide sequence of SEQ ID NO:56 or the polypeptide encoded by the HYACJ27 cDNA contained in ATCC Deposit No. PTA-163). Accordingly, Applicants respectfully submit that one skilled in the art would reasonably conclude that Applicants had possession of the polypeptides encompassed by the pending claims in the present application as filed. Hence, Applicants respectfully request that the rejection of the previously pending and newly amended claims 24-75 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Claim Rejections - 35 U.S.C. § 101

Claims 11, 12, 14 and 24-75 were rejected in the outstanding Office Action under 35 U.S.C. § 101, for allegedly lacking "patentable utility, due to its not being supported by either

[a] specific or substantial asserted utility or a well-established utility." *See*, Paper No.9, page 5, last paragraph.

Applicants have herein canceled claims 11, 12, and 14 without prejudice or disclaimer and, therefore, submit that the rejection of these claims has been rendered moot. Applicants reserve the right to pursue the subject matter of claims 11, 12, and 14 in one or more divisional applications.

Additionally, as discussed in Applicants June 26th interview with the Examiner (*see*, Paper No. 10), the specification as originally filed does assert a specific and substantial utility for the presently claimed polypeptides. That is, as recorded in Paper No. 10, the claimed polypeptides are useful as a marker for B-cell lymphoma. Accordingly, as a result of the interview, the rejection of claims 24-75 under 35 U.S.C. § 101, first paragraph, was reconsidered and withdrawn. Again, Applicants thank the Examiner and his supervisor for the interview with Applicants counsel.

Conclusion

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: July 9, 2002

Janet M. Martineau (Reg. No. 46,903)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, Maryland 20850
301-315-2723 (telephone)

KKH/JMM/DAS

Docket No.: PZ040P1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ruben et al.

Application No.: 09/726,643 Group Art Unit: 1656

Filed: December 1, 2000 Examiner: A. Spiegler

For: 26 Human Secreted Proteins

Version With Markings To Show Changes Made

(Underline = inserted text, ~~Strike through~~ = deleted text)

Claims 36, 38-56, 61, 66, and 71 have been amended as follows:

-- 36. An isolated first polypeptide at least 90% identical to a second polypeptide consisting of amino acid residues 19 to 79 of SEQ ID NO:56, wherein said first polypeptide is capable of being used to generate or select an antibody that specifically binds the second polypeptide.

38. The isolated first polypeptide ~~protein~~ of claim 36 which further comprises a polypeptide sequence heterologous to SEQ ID NO:56.

39. A composition comprising the isolated first polypeptide ~~protein~~ of claim 36 and an acceptable carrier.

40. An isolated protein produced by the method comprising:

(a) expressing the isolated first polypeptide ~~protein~~ of claim 36 by a cell; and

(b) recovering said protein.

41. An isolated first polypeptide at least 90% identical to a second polypeptide consisting of the secreted portion of the polypeptide encoded by the HYACJ27 cDNA contained in ATCC Deposit No. PTA-163, wherein said first polypeptide is capable of being used to generate or select an antibody that specifically binds the second polypeptide.

42. The isolated first polypeptide of claim 41, wherein said first polypeptide is at least 95% identical to the said second polypeptide.

43. The isolated first polypeptide ~~protein~~ of claim 41 which further comprises a polypeptide sequence heterologous to SEQ ID NO:56.

44. A composition comprising the isolated first polypeptide ~~protein~~ of claim 41 and an acceptable carrier.

45. An isolated protein produced by the method comprising:

(a) expressing the isolated first polypeptide ~~protein~~ of claim 41 by a cell; and

(b) recovering said protein.

46. An isolated first polypeptide at least 90% identical to a second polypeptide consisting of amino acid residues 1 to 79 of SEQ ID NO:56, wherein said first polypeptide is capable of being used to generate or select an antibody that specifically binds the second polypeptide.

47. The isolated first polypeptide of claim 46, wherein said first polypeptide is at least 95% identical to said second polypeptide.

48. The isolated first polypeptide ~~protein~~ of claim 46 which comprises a heterologous polypeptide sequence.

49. A composition comprising the isolated first polypeptide ~~protein~~ of claim 46 and an acceptable carrier.

50. An isolated protein produced by the method comprising:

(a) expressing the isolated first polypeptide ~~protein~~ of claim 46 by a cell; and

(b) recovering said protein.

51. An isolated first polypeptide at least 90% identical to a second polypeptide consisting of the complete polypeptide encoded by the HYACJ27 cDNA contained in ATCC Deposit No. PTA-163, wherein said first polypeptide is capable of being used to generate or select an antibody that specifically binds the second polypeptide.

52. The isolated first polypeptide of claim 51, wherein said first polypeptide is at least 95% identical to said second polypeptide.

53. The isolated first polypeptide ~~protein~~ of claim 51 which further comprises a polypeptide sequence heterologous to SEQ ID NO:56.

54. A composition comprising the isolated first polypeptide ~~protein~~ of claim 51 and an acceptable carrier.

55. An isolated protein produced by the method comprising:

(a) expressing the isolated first polypeptide ~~protein~~ of claim 51 by a cell; and

(b) recovering said protein.

56. An isolated protein consisting of at least 30 contiguous amino acid residues of amino acid residues 19 to 79 of SEQ ID NO:56, wherein said protein is capable of being used to generate or select an antibody that specifically binds a polypeptide comprised of amino acid residues 19 to 79 of SEQ ID NO:56.

61. An isolated protein consisting of at least 30 contiguous amino acid residues of the secreted portion of the protein ~~polypeptide~~ encoded by the HYACJ27 cDNA contained in ATCC Deposit No. PTA-163, wherein said first protein is capable of being used to generate or select an antibody that specifically binds the second protein.

66. An isolated protein consisting of at least 30 contiguous amino acid residues of amino acid residues 1 to 79 of SEQ ID NO:56, wherein said protein is capable of being used to generate or select an antibody that specifically binds a polypeptide comprised of amino acid residues 1 to 79 of SEQ ID NO:56.

71. An isolated protein consisting of at least 30 contiguous amino acid residues of the complete protein ~~polypeptide~~ encoded by the HYACJ27 cDNA contained in ATCC Deposit No. PTA-163, wherein said first protein is capable of being used to generate or select an antibody that specifically binds the second protein. --